

**REMARKS/ARGUMENTS**

As an initial matter, Applicants wish to thank the Examiner for indicating claims 32, 33, 36-38, 63, 85, 92 and 97 as allowable in the Office Action dated September 29, 2003.

(Office Action at 7.)

I. **Status of the Claims**

By the present amendment, originally presented claims 1-103 have been cancelled without prejudice or disclaimer and new claims 104-261 have been added. Support for the present amendment may be found in the specification as originally filed, including the original claims. Therefore, no new matter has been added.

New claims 104-177 incorporate the subject matter of original claims 32, 33, 36-38, 63, 85, 92 and 97, indicated as allowable in the Office Action. These new claims, with the corresponding original claims indicated as allowable, are shown in the following table.

New Claims	Support
104, 105 and claims dependent therefrom*	Original Claim 32
121, 122 and claims dependent therefrom*	Original Claim 63
140, 141 and claims dependent therefrom*	Original Claim 37
144-147 and claims dependent therefrom*	Original Claim 92
148-151	Original Claim 97
174 and 175	Original Claim 36
177	Original Claim 85

\*The dependent claims correspond to original dependent claims 5-31, 33-35, 38-53, 56-62, 64-84, 86-91, 93-96 and 98-101.

Additionally, new claims 178-261 have been added. As recited in new claims 178-261, the rate of irradiation not constant and comprises a rate of between about 0.1kGy/hr to 3.0kGy/hr for at least a portion of the period of irradiation and a rate of at least 6.0kGy/hr for at least

another portion of the period of irradiation. Support for this limitation may be found in the specification as originally filed, for instance, paragraphs 113 through 119. The undersigned notes that this limitation is the same as that recited in independent claim 1 of U.S. Patent No. 6,682,695, which issued from U.S. Patent Application No. 10/197,248.

## II. Response to the Grounds of Rejection

In the outstanding Office Action, the Office made the following grounds of rejection:

- (A) Claims 1-4, 15-26, 28-30, 34, 35, 39-42, 55-62, 64-71, 74-84, 86-91, 96, and 98-103 under 35 U.S.C. § 102(b) as allegedly anticipated by Peterson (U.S. Patent No. 5,730,933);
- (B) Claims 1, 11-14, 28, 49, 53, 86-88, 96, and 98-103 under 35 U.S.C. § 102(b) as allegedly anticipated Odland (U.S. Patent No. 5,989,498);
- (C) Claims 54, 65, and 93 are rejected under 35 U.S.C. § 102(b) as allegedly anticipated by Horowitz et al (U.S. Patent No. 5,981,163);
- (D) Claims 5, 27, and 31 under 35 U.S.C. § 103(a) as allegedly unpatentable over Horowitz et al.;
- (E) Claims 6-9 are rejected under 35 U.S.C. § 103(a) allegedly unpatentable over Peterson in view of Kent; and
- (F) Claims 2, 6-9, 27-31, 34, 35, 39-50, 53, 72, 73, 86, 87, 90, 91, 94, 95, and 98-103 are rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Horowitz et al. in view of Kent.

Applicants respectfully traverse these rejections, and respectfully submit that the rejections are moot for at least the following reason. Originally presented claims 1-103, as discussed above,

have been cancelled. New claims 104-177 have been added, which encompass the subject matter indicated as allowable by the Examiner, i.e., original claims 32, 33, 36-38, 63, 85, 92 and 97. Since these claims recite subject matter indicated as allowable in the Office Action, the prior art of record fails to teach or to suggest the invention as recited in new claims 104-177 for at least the reasons noted by the Examiner in the Office Action with respect to original claims 32, 33, 36-38, 63, 85, 92 and 97 (Office Action at 7). Therefore, these grounds of rejection should be withdrawn.

Regarding new claims 178-261, the undersigned respectfully submits that the prior art of record fails to teach or to suggest methods for sterilizing biological materials, as presently claimed, wherein the rate of irradiation is not constant and comprises a rate of between about 0.1kGy/hr to 3.0kGy/hr for at least a portion of the period of irradiation and a rate of at least 6.0kGy/hr for at least another portion of the period of irradiation. Therefore, for at least this reason, new claims 178-261 are allowable over the prior art of record.

As indicated above, this limitation, *viz.*, the rate of irradiation is not constant and comprises a rate of between about 0.1kGy/hr to 3.0kGy/hr for at least a portion of the period of irradiation and a rate of at least 6.0kGy/hr for at least another portion of the period of irradiation, is the same as that recited in independent claim 1 of U.S. Patent No. 6,682,695 which issued from U.S. Patent Application No. 10/197,248. As noted by the Examiner in that related application, the prior art fails to teach or to suggest methods for sterilizing biological materials wherein the dose rate is increased during the course of irradiation (see U.S. Patent Application No. 10/197,248, Office Action dated July 7, 2003). Therefore, new claims 178-261 are allowable

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over the prior art of record, since the prior art of record fails to teach or suggest methods wherein the rate is not constant and includes the specific rates enumerated in claims 178-261.

**CONCLUSION**

In view of the foregoing amendments and remarks, it is respectfully submitted that the application is in condition for allowance. If the Examiner believes that any additional changes would place the application in better condition for allowance, the Examiner is invited to contact the undersigned representative, Timothy M. Speer, at the telephone number listed below. Favorable consideration and prompt allowance are earnestly solicited.

To the extent necessary, a petition for an extension of time under 37 C.F.R. 1.136 is hereby made. Please charge any shortage in fees due in connection with the filing of this, concurrent and future replies, including extension of time fees, to Deposit Account 16-0607 and please credit any excess fees to such deposit account.

Respectfully submitted,  
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